

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
MEDTRONIC, INC.,
SPRINT FIDELIS LEADS
PRODUCTS LIABILITY LITIGATION

Multidistrict Litigation
No. 08-1905 (RHK/JSM)

THIS DOCUMENTS RELATES
TO ALL CASES

ORDER NO. 2
(Modifying Pretrial Order No. 1)

This matter is before the Court upon Defendants' Emergency Motion to Vacate or Modify the Order for the Preservation of Evidence and for Entry of Substitute Order [Docket No. 13].

Having considered the various submissions by Medtronic and the Certain Plaintiffs bearing on this motion, including these parties' respective responses to this Court's Order dated May 1, 2008,

IT IS HEREBY ORDERED

Subparagraph 4(d) of Pretrial Order No. 1 (Setting Initial Conference), dated April 23, 2008 [Docket No. 12] is vacated. Until further order of the Court, the parties will abide by the preservation obligations set forth below in this Order.

4(d) Preservation of Records and Evidence.

- i. The parties shall take good-faith reasonable steps, including due diligence, to preserve all documents, records and electronically-stored information within their possession, custody, or control that contain information that is potentially relevant to the subject matter of this litigation. Notwithstanding the foregoing, subject to further order of the Court, a party may continue routine erasures of computerized data

pursuant to existing programs that contain information potentially relevant to the claims, defenses or the subject matter of this litigation providing that the party (1) immediately notifies opposing counsel about such programs, and (2) makes a printout of the data containing potentially relevant information before it is erased.

- ii. Each party shall preserve any physical evidence within their possession, custody, or control containing information that is potentially relevant to the claims, defenses or subject matter of this litigation. In this regard, a party shall not conduct any testing that alters physical evidence without notifying opposing counsel and, unless counsel stipulate to the test, without obtaining the Court's permission to conduct the test. Notwithstanding the foregoing, and subject to further order of the Court:

(A) Medtronic may do the following non-destructive testing and analysis on Explanted Sprint Fidelis Leads¹, Other Sprint Fidelis Leads²,

¹ “Explanted Sprint Fidelis Leads” for the purpose of this Order means those leads marketed by Medtronic under the following model numbers that have been returned to Medtronic after being explanted from a patient:

1. the 6949 LFJ extendable/retractable screw fixation (S) model;
2. the 6948 LFH tined fixation (T) model;
3. the 6931 LFT S fixation model; and
4. the 6930 LFK T fixation model

² “Other Sprint Fidelis Leads” for the purpose of this Order means those leads marketed by Medtronic under the model numbers identified in footnote 1 that have been the subject of research in the laboratory without having been implanted.

and Returned Implanted Products³: (1) reprogramming to turn the ventricular fibrillation detection therapy “off,” if it is programmed “on;” (2) interrogation utilizing a Medtronic programmer; (3) recording continuity and electrical testing; (4) creating a Save-to-Disk file of data extracted from such products; (5) importing the Save-to-Disk file to any associated data system, including but not limited to Medtronic internal regulatory reporting systems; (6) photographing; and (7) decontaminating and sterilizing. The information obtained using the Medtronic programmer and the Save-to-Disk process shall be preserved. All Explanted Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products shall be retained by Medtronic.

(B) Any plaintiff in possession of surgically removed Medtronic products, other than Explanted Sprint Fidelis Leads, that were implanted together with Sprint Fidelis Leads, shall return such devices, if they have not done so already, within thirty (30) days of the date of this Order, to a representative of Medtronic that shall be designated in writing by Medtronic within ten (10) days of entry of this Order. Plaintiff shall maintain chain of custody information for such devices.

(C) Each device received pursuant to Subparagraph (B), above, shall be considered to be Returned Implanted Products, as defined above

³ “Returned Implanted Products” for the purpose of this Order means other Medtronic products that have been returned to Medtronic that, through reasonable efforts, can be identified as having been implanted together with the Sprint Fidelis Leads identified in footnote 1, including other lead models, implantable cardioverter defibrillators (“ICDs”), and implantable pulse generators (“IPGs”) (collectively,). ”

in this Order and will be subject, as appropriate, to the testing and analysis provisions detailed above in Subparagraph (A).

Dated: May 14, 2008

s/Janie S. Mayeron
JANIE S. MAYERON
United States Magistrate Judge

MEMORANDUM

On April 23, 2008, this Court issued Order No. 1 [Docket No. 12], which included an interim measure for the preservation of records. See Order No. 1, Paragraph 4(d). Medtronic then filed an Emergency Motion to Vacate or Modify the Order for the Preservation of Evidence and for Entry of Substitute Order [Docket No. 13]. Specifically, Medtronic sought to have this Court enter an interim preservation order similar to Order for the Preservation of Evidence entered on December 12, 2007 in Russell-Nelson et al. v. Medtronic, Inc. et al. (the “Puerto Rico litigation”). Certain plaintiffs objected to Medtronic’s proposed substitute preservation order, arguing among other reasons, that most of the plaintiffs (and their respective counsel) in the instant MDL case were not part of the Puerto Rico litigation.

There is no question that the parties and Court must devise a preservation order that takes into account the parties’ countervailing needs: the need to retain relevant information bearing on this litigation, and Medtronic’s need to meet its business obligations, patient safety and regulatory requirements by continuing to engage in the testing and analysis of the leads and associated products that are the subject matter of this litigation. At the same time, the Court is cognizant of the fact that it will be putting in

place a preservation order that affects many cases and thousands of plaintiffs who have yet to have an opportunity to speak on the contents of such an order. The question is what to do in the interim, i.e. before the initial conference occurs on May 28, 2008, and a process is put in place for all parties to express their needs and concerns.

Based on the submissions of Medtronic and certain plaintiffs, this Court concludes that Medtronic can proceed with nondestructive testing and analysis of the Explanted Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products as set forth in this Order.⁴ At the same time, the Court is not satisfied that the balance of Medtronic's proposed preservation order (e.g. permitting destructive testing of Other Sprint Fidelis Leads and Returned Implanted Products) should be put in place until the mechanisms have been adopted by this Court for all plaintiffs to have input into the contents of and their respective obligations under a preservation order.

That said, the Court has also included a mechanism for plaintiffs in possession of surgically removed Medtronic products, other than Explanted Sprint Fidelis Leads, that were implanted together with Sprint Fidelis Leads, to return these other products to Medtronic (which is then permitted to perform nondestructive testing and analysis on them). The Court included this provision because of the representations by Medtronic that certain data containing potentially relevant information may reside in these products that will be lost if it is not promptly extracted and saved before the product's batteries go dead. See Medtronic Mem. at pp. 13, 16 [Docket No. 27].

Finally, the Court has clarified the parties' obligations with respect to preservation of documents, records and electronically-stored information, including the obligation to

⁴ The Court notes that the Certain Plaintiffs did not object to Paragraph C.1 (Non-Destructive Testing and Analysis) of Medtronic's proposed preservation order.

preserve a printout of any computerized data that is routinely erased, if it contains information potentially relevant to this litigation. .

J.S.M.